

EXHIBIT B

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Premarket Approval (PMA)



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Note: this medical device has supplements. The device description may have changed. Be sure to look at the supplements to get an up-to-date view of this device.

Trade Name MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM
Classification Name [Pump, Infusion, Implanted, Programmable](#)²³
Generic Name Implanted Infusion Pump
Applicant MEDTRONIC INC.
PMA Number P860004
Date Received 02/03/1986
Decision Date 03/14/1988
Product Code LKK [[Registered Establishments With LKK](#)²⁴]
Docket Number 88M-0114
Notice Date 05/11/1988
Advisory Committee General Hospital
Expedited Review Granted? No
Combination Product [Yes](#)²⁵
Recalls

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Premarket Approval (PMA)

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2. Premarket Approval (PMA)

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224. /scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P860004&SupplementNumber=S216